4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0482]

Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drug Applications and Veterinary Master Files

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information associated with new animal drug applications and veterinary master files.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-N-0482 for "New Animal Drug Applications and Veterinary Master Files." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those

submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

New Animal Drug Applications and Veterinary Master Files

OMB Control Number 0910-0032--Extension

This information collection supports implementation of section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b), which governs new animal drugs. Agency regulations in 21 CFR part 514 and associated regulations in 21 CFR part 558, establish

format and content requirements regarding new animal drug application (NADA) submissions, as well as provide for pre-application submissions, amended applications, and application supplements. This information collection also supports implementation of section 571 of the FD&C Act (21 U.S.C. 360ccc) regarding application for conditional approval of new animal drug (CNADA) submissions. As set forth in the FD&C Act and Agency regulations, requisite elements include safety and effectiveness data, proposed labeling, product manufacturing information, and, where necessary, complete information on food safety (including microbial food safety) and any methods used to determine residues of drug chemicals in edible tissue from food producing animals. Applications must be prepared as appropriate to support the particular submission. Respondents to the information collection are persons developing, manufacturing, and/or researching new animal drugs.

We developed Form FDA 356v (Application for Approval of a New Animal Drug (or Submission to Support New Animal Drug Approval)) to provide a uniform format for submitting requisite information and to ensure efficient processing by the Agency. Form FDA 356v is available for download from our website at https://www.fda.gov/about-fda/reports-manuals-forms/forms. We also develop Agency guidance documents that may assist respondents with understanding NADA/CNADA requirements and related information collection activity. This includes FDA Guidance #152[1], which outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs and includes Agency recommendations in this regard.

Under section 512(b)(3) of the FD&C Act, any person intending to file a NADA or supplemental NADA or a request for an investigational exemption under section 512(j) of the FD&C Act may request a conference prior to making a submission. Section 514.5 of our regulations (21 CFR 514.5) sets forth procedures for presubmission conferences and describes

[1] Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-152-evaluating-safety-antimicrobial-new-animal-drugs-regard-their-microbiological-effects.

documentation associated with making requests, and preparing for and conducting meetings. We encourage sponsors to submit data for review at the most appropriate and productive times in the drug development process. Rather than submitting all data for review as part of a complete application, we have found that the submission of data supporting discrete technical sections during the investigational phase is most appropriate and productive. This "phased review" of data submissions has created efficiencies for us and the animal pharmaceutical industry.

We also encourage, as appropriate, the submission of a veterinary master file (VMF). For more information on VMFs, we invite you to visit https://www.fda.gov/animal-veterinary/development-approval-process/veterinary-master-files. A VMF provides detailed information used in support of application submissions. Questions regarding VMF submissions may be directed to our Center for Veterinary Medicine at cvmesubmitter@fda.hhs.gov. We have found that utilizing VMFs has increased the efficiency of the animal drug development and animal drug review processes for FDA and the animal pharmaceutical industry, providing for the confidential exchange of information with FDA and a process for reporting information outside of a NADA/CNADA or an investigational new animal drug file, as well as an opportunity for increased communication with FDA during the early stages of product development. A holder of a VMF may also authorize other parties to reference information included in the VMF without disclosing information in the file to those parties. VMFs can be used as repositories for information that can be referenced in multiple submissions to the Agency.

Section 558.5(i) of FDA regulations (21 CFR 558.5(i)) describes the procedure for requesting a waiver of the labeling requirements in § 558.5(h) in the event that there is evidence to indicate that it is unlikely a new animal drug would be used in the manufacture of a liquid medicated feed.

Finally, section 571 of the FD&C Act establishes requirements for the conditional approval of certain drugs[2] and the procedures for submitting applications for conditional approval. Although FDA receives fewer than one application submission under section 571 of the FD&C Act annually when averaged over a 3-year period, we use a placeholder of one response and 1 hour annually to account for the burden associated with these submissions.

Information collection associated with NADAs/CNADAs and related submissions is necessary to ensure that new animal drugs are in compliance with sections 512(b)(1) and 571 of the FD&C Act. We review the information, including data, labeling, and manufacturing controls and procedures, to evaluate the safety and effectiveness of the proposed new animal drug.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§§ 514.1 and 514.6; applications and amended applications	187	0.07	13	212	2,756
§§ 514.1(b)(8) and 514.8(c)(1)[2]; evidence to establish safety and effectiveness	187	0.44	82	90	7,380
§ 514.5(b), (d), and (f); requesting presubmission conferences	187	0.67	125	50	6,250
§ 514.8(b); manufacturing changes to an approved application	187	2	374	35	13,090
§ 514.8(c)(1); labeling and other changes to an approved application	187	0.06	11	71	781
§ 514.8(c)(2) and (3); labeling and other changes to an approved application	187	0.84	157	20	3,140
§ 514.11; submission of data studies and other information	187	0.13	24	1	24
§ 558.5(i); requirements for liquid medicated feed	187	0.01	2	5	10
Applications for conditional approval submitted under section 571 of the FD&C Act	1	1	1	1	1
Form FDA 356V	187	36.5	6,825	0.75 (45 minutes)	5,118
VMF submissions	15	1	15	20	300
Total			7,628		38,849

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] Animal drugs intended for use in minor species, minor use in major species, or for serious or life-threatening conditions or unmet animal or human health needs where a demonstration of effectiveness would require a complex or particularly difficult study or studies.

[2] NADAs and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall preapproval safety evaluation.

Although we have characterized the information collection activity as a reporting burden, we include in our estimate time required for searching data sources, and preparing and maintaining necessary and applicable records. As stated above, although we receive fewer than one submission annually when averaged over a 3-year period, we attribute one response and 1 hour annually to account for CNADA submissions

We have adjusted our estimate of the information collection to reflect a decrease in burden associated with application submissions in acknowledgement of respondents' preference in using FDA's "eSubmitter" system, which automatically generates Form FDA 356v and allows respondents to complete the form and submit applications and associated information electronically.

Dated: February 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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